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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,262	08/27/2003	Yerramilli V.S.N. Murthy	61635-5016	6595

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/650,262	MURTHY ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-14 and 44-70*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/D. J./
Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because: Regarding the statement at page 3 of the office action regarding the indefiniteness of claims 1-14, 45-54 and 56-57, this is an indefinite rejection that was present in the office action dated May 4, 2007 (see page 5 for clarification). The examiner regrets that the beginning of the rejection was accidentally cut off. The rejection is a repeat of the 35 USC §112, second paragraph rejection over claim 1 regarding the use of the words "over time". This is not a new rejection. Regarding the rejection of claim 1 over Kanios et al., applicant asserts that the prior art is completely different from a composition described as suitable for oral administration or administration by injection. In response, without any further information about the composition "suitable for oral administration or an injectable composition, the prior art obviates the claim. In response to applicant's argument that Kanios differs because it is drawn to a topical composition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Although it may be distasteful, the composition of Kanios is capable of being swallowed. Applicant has not set forth in the claim, limitations that would make the composition suitable or unsuitable for oral administration or for parenteral use. Applicant asserts that oral administration means administration by swallowing. The phrase "to form a composition for oral administration or an injectable composition is viewed as intended use and therefore is generally not accorded any patentable weight. It merely recites the intended use of the composition and the body of the claim does not depend on it for completeness. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any jedgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from applicant's discosure, such a redconstructino is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant asserts that the examiner selects fluoxeting from a laundry list of pharmacologically active compounds that spans more than 19 columns. In response, picking and choosing known components, each which itself discloses a plurality of such components, is permissible where each component has the same individual utility. In re Dial, 326 F .2d 430 (CCPA 1964). (holding that it would have been obvious to have combined four individual stabilizers for halogenated hydrocarbon solutions from three different references, where there was no evidence in the record establishing that Applicants' claimed combination of stabilizers was nay more effective or in any way otherwise different in inhibiting the decomposition of halogenated hydrocarbons than any single member of that combination. Id. at 432.).

Regarding applicants assertion that Shojaci does not disclose each and every feature of the invention recited in independent claims 1 and 44 or provide reasonable expectation of success, It is prima facie obvious to select a known material based on its suitability for its intended use. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430,432 (CCPA 1964). REgarding applicants argument that Shojaci discloses capsules filled with NMP which is a water miscible solvent, a reference is not limited to working examples. In re Fracalossi 215 USPQ 569 (CCPA 1982). Regarding applicants assertion that Williams does not teach a lipophilic counterion, the claim recites a composition comprising a salt of the pharmacologically active compound with a lipophilic counterion and a water immiscible solvent. The lipophilic counterion can be an ionized form of a C10-C22 saturated or unsaturated fatty acid. The caprylic acid of Williams et al. meets the claim limitatation. Applicant asserts that there is no disclosure or suggestion in Williams of a salt formed between a pharmacologically active compound and a lipophilic counterion. In response, the claim is drawn to a a composition comprising a salt of the pharmacologically active compound "with" a lipophilic counterion and a pharmaceutically acceptable water immiscible solvent. The claim does not recite that the salt must form between the pharmacologically active compound and a lipophilic counterion and then combine the "resulting salt with a water immiscible solvent". Regarding applicants assertion that Patel does not disclose each and every feature of the invention recited in independent claims 1 and 44, suggest the invention or provide a reasonable expectation of success. In response, Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and "lipophilic counter ions", "water immiscible solvents" or "clear solutions". However, "Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. Applicant asserts that there is no disclosure or suggestion in Patel of a salt formed between a pharmacologically active compound and a lipophilic counterion. In response, the claim is drawn to a a composition comprising a salt of the pharmacologically active compound "with" a lipophilic counterion and a pharmaceutically acceptable water immiscible solvent. The claim does not recite that the salt must form between the pharmacologically active compound and a lipophilic counterion and then combine the "resulting salt with a water immiscible solvent". Regarding the non-statutory obviousness-type double patenting rejection over claims 65-138 of co-pending 11/088,922, applicant has requested that the rejection be held in abeyance until all rejections of the claims over prior art have been addressed.